Anti-Infective Subcommittee of PTAC meeting held 13 October 2010

(minutes for web publishing)

Anti-Infective Subcommittee minutes are published in accordance with the *Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees 2008*.

Note that this document is not necessarily a complete record of the Anti-Infective Subcommittee meeting; only the relevant portions of the minutes relating to Anti-Infective Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are generally published.

The Anti-Infective Subcommittee may:

(a) recommend that a pharmaceutical be listed by PHARMAC on the Pharmaceutical Schedule and the priority it gives to such a listing;
(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or
(c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

These Subcommittee minutes were reviewed by PTAC at its meeting on 17 & 18 February 2011, the record of which is available on the PHARMAC website.

Contents

1 Moxifloxacin funding under Exceptional Circumstances

1.1 The Subcommittee noted the requirements for approval of funding pharmaceuticals under Community and Hospital Exceptional Circumstances (CEC and HEC respectively). Members noted that the sole criterion of the HEC scheme is that the treatment requested is cost saving to the DHB Hospital than the most likely alternative intervention or outcome. This Scheme was originally designed to allow patients to be discharged from hospital into the community on a medicine which was otherwise only available in hospital. The Subcommittee noted that the types of indications are too common for the applications to meet the rarity criteria of the Community EC scheme.

1.2 The Subcommittee noted the current PHARMAC proposal for Pharmaceutical Schedule listing for moxifloxacin for mycobacterium indications.

1.3 Members noted that HEC Panel was receiving a significant number of applications for non-tuberculosis pneumonia in a variety of circumstances and noted that technically applications for short-term treatment could meet the HEC criterion. The HEC Panel was aware of previous Anti-infective Subcommittee advice to restrict quinolone usage due to resistance and that under the HEC criterion, the Panel must consider the funded alternative treatments available before an unfunded medicine can be considered. Therefore, the Panel had sought the Subcommittee's guidance on the most appropriate approach to determine these HEC applications.

1.4 The Subcommittee considered that for paediatric cases moxifloxacin was rarely used.

1.5 The Subcommittee considered that for the treatment of legionella, a macrolide or doxycycline, should be considered as first line therapy and if a quinolone was required then ciprofloxacin should be used. Members noted that in certain clinical situations ciprofloxacin could be considered as a first line agent. Members considered that moxifloxacin should not be funded/approved for legionella.

1.6 The Subcommittee noted that neither ciprofloxacin nor cefuroxime should be used in penicillin resistant pneumococcal infection and therefore neither ciprofloxacin nor cefuroxime were suitable funded alternatives for this indication.

1.7 The Subcommittee considered that the minimum requirements for considering moxifloxacin in resistant pneumococcal therapy were having an organism isolated, sensitivities and ideally Minimum Inhibition Concentration (MIC). Members considered that for many pneumococcal infections an intra-venous beta-lactam would allow MIC to be reached; however, penetration with oral penicillin was not sufficient to reach MIC.

1.8 The Subcommittee **recommended** that the HEC Panel consider approving proven resistant pneumococcal infection if the MIC required for using beta-lactams or macrolides was not possible via oral therapy. Members **recommended** that if no sensitivities were provided or no organism was isolated then the application should be declined.

1.9 The Subcommittee considered that it was not appropriate to define a Special Authority for moxifloxacin for non-mycobacterium indications at this time as there would likely be slippage around such criteria resulting in significant inappropriate prescribing.

2 Clarithromycin

2.1 The Subcommittee noted the Special Authority for clarithromycin was changed in 1998. Members considered that the current Special Authority was no longer appropriate. Members noted that it was no longer clinical practice for clarithromycin to be prescribed for prophylaxis in HIV infection.

2.2 The Subcommittee **recommended** that the Special Authority for clarithromycin be amended as follows (changes in bold, deletions in strikethough):

Initial application - (Mycobacterial infections) only from a ~~respiratory specialist, infectious disease specialist or paediatrician~~ **VRMP in Internal Medicine or Paediatrics**. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

~~1 Mycobacterium Avium Intracellulare Complex infections in patient with AIDS; or~~

~~2~~**1** Atypical ~~and drug-resistant~~ mycobacterial infection; or

2 Mycobacterium tuberculosis infection where there is drug-resistance or intolerance to standard pharmaceutical agents.

3 ~~All of the following:~~

~~3.1 Prophylaxis against disseminated Mycobacterium Avium Intracellulare Complex infection; and~~

~~3.2 HIV infection; and~~

~~3.3 CD4 count <= 50 cells/mm3.~~

Renewal - (Mycobacterial infections) only from a ~~respiratory specialist, infectious disease specialist or paediatrician~~ **VRMP in Internal Medicine or Paediatrics**. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

3 Ornidazole

3.1 The Subcommittee noted that the current supplier of ornidazole in New Zealand had notified of discontinuation of this product. Members noted that tinidazole had been discontinued in New Zealand. Members considered that with the discontinuation of tinidazole that ornidazole was first line therapy for the treatment of giardia.

3.2 Members noted that giardia infection was a significant health burden in New Zealand.

3.3 The Subcommittee noted that ornidazole was an important therapy to maintain as it provided a single dose therapy for giardia. Members noted that metronidazole could be

prescribed for giardia however, it was a longer course. Members considered that compliance was a potential issue due to the increase length of course and the side-effect profile of metronidazole.

3.4 The Subcommittee **recommended** that PHARMAC investigate the possibility of re-listing tinidazole.

3.5 The Subcommittee **recommended** that ornidazole be retained with a medium/high priority.

4 Fluconazole

4.1 The Subcommittee noted the tabled documents detailing the process for removing the restrictions from fluconazole. Members noted the information from PHARMAC regarding the Health Practitioners Competence Assurance Act and the rationale and implications of targeting prescriber rather than patient groups.

4.2 The Subcommittee reviewed the responses to PHARMACs 24 April 2010 consultation on removing the restrictions from fluconazole capsules. Members noted the concern from clinicians regarding the risk of increased resistance if there was a significant increase in prescribing of fluconazole as a result of widening funded access.

4.3 The Subcommittee noted that fluconazole 150 mg capsules were available for purchase in the community after consultation with a pharmacist. Members considered there may be an access issue for patients as the cost from pharmacy may be prohibitive for some patients.

4.4 The Subcommittee considered that a restriction on the number of capsules that could be prescribed would reduce the risk of resistance. The Subcommittee **recommended** that a restriction of one capsule should be applied for fluconazole 150 mg capsules.

4.5 The Subcommittee considered that an endorsement should also be applied to the dispensing of fluconazole in line with the New Zealand Sexual Health Service Guidelines. The Subcommittee **recommended** that the following endorsement be applied

> Patient has vaginal candida albicans and the authorised prescriber considers that a topical imidazole is not recommended

4.6 The Subcommittee noted the restrictions applying to fluconazole 50 mg and 200 mg. Members considered that fluconazole 50 mg or 200 mg should only be used for systemic fungal infections. The Subcommittee **recommended** retaining a restriction for Vocationally Registered Medical Practitioner Internal Medicine or Paediatrics.